

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	
_____	)	MDL NO. 1203
	)	
THIS DOCUMENT RELATES TO:	)	
	)	
SHEILA BROWN, et al.	)	
	)	CIVIL ACTION NO. 99-20593
v.	)	
	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

**MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.**

Bartle, C.J.

July 2, 2010

Evelyn V. Gierse a/k/a Viola Gierse ("Ms. Gierse" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>2</sup> Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>3</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Oliver E. Gierse, Ms. Gierse's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Randall G. Johnson, M.D. Based on an echocardiogram dated May 22, 2003, Dr. Johnson attested in Part II of Ms. Gierse's Green Form that claimant suffered from moderate aortic regurgitation and a reduced ejection fraction in the range of 40% to 49%.<sup>4</sup> Based on

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3. (...continued)  
medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. Dr. Johnson also attested that claimant suffered from mild mitral regurgitation, an abnormal left ventricular end-systolic  
(continued...)

such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$207,947.<sup>5</sup>

In the report of claimant's echocardiogram, Dr. Johnson stated that Ms. Gierse had "[m]ild to moderate aortic insufficiency." Dr. Johnson did not specify a percentage as to the level of claimant's aortic regurgitation. Under the definition set forth in the Settlement Agreement, moderate aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable) is 25% to 49% of the left ventricular outflow tract height ("LVOTH"). See Settlement Agreement §§ I.22 & IV.B.2.c.(2)(a). In addition, although Dr. Johnson initially estimated claimant's ejection fraction as 60%, he subsequently issued a revised echocardiogram report dated July 13, 2004 in which he stated that claimant had an "[e]stimated ejection fraction of 40 percent."<sup>6</sup> An ejection

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4. (...continued)  
dimension greater than or equal to 45 mm by M-Mode or 2-D echocardiogram, an abnormal left atrial dimension, mitral annular calcification, arrhythmias, and New York Heart Association Functional Class I symptoms. These conditions, however, are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the aortic valve if he or she is diagnosed with moderate or severe aortic regurgitation and one of three complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(a). An ejection fraction less than 50% is one of the complicating factors.

6. In a handwritten note in the Green Form, Dr. Johnson  
(continued...)

fraction is considered reduced for purposes of an aortic valve claim if it is measured as less than 50%. See id.

§ IV.B.2.c.(2)(a)iii).

In July, 2005, the Trust forwarded the claim for review by Robert Skotnicki, D.O., F.A.C.C., F.S.C.A.I., one of its auditing cardiologists. In audit, Dr. Skotnicki concluded that there was no reasonable medical basis for Dr. Johnson's finding that claimant had moderate aortic regurgitation. In support of this conclusion, Dr. Skotnicki explained that:

The Singh criteria were not followed to define severity of [aortic insufficiency]. The jet height and [LVOTH] were not measured by the sonographer. The auditor measured the [aortic insufficiency] jet height (0.5 cm) and the [LVOTH] (2.2 cm). The [JH/LVOTH] was less than 24%. The interpreting cardiologist and the report do not provide method/mechanism as to how the amount of [aortic insufficiency] was quantitated. Therefore, the criteria specified on the Green Form in section C3 regarding aortic insufficiency were not met.

Dr. Skotnicki also concluded that there was no reasonable medical basis for the attesting physician's conclusion that claimant had a reduced ejection fraction, finding that:

The left ventricle contracts very efficiently in all segments and all views. The basis for the interpreting cardiologist['s] estimate of 40% [is] not documented in the record. The second page of the echo report, a printout

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6. (...continued)

explained the revised echocardiogram report as follows:

"Mrs. Gierse was seen in my office on May 22, 2003. The original written report of that echo had a typo regarding the ejection fraction. The ejection fraction was 40% as seen on the attached Cardiac M-Mode report."

from the echo machine, is not legible....  
[T]he [parasternal long-axis] and the  
[parasternal short-axis] as well as the  
apical window shows the [left ventricle]  
contracting with much vigor. At no time in  
any view does the [left ventricle] not appear  
to contract very well.

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying Ms. Gierse's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>7</sup> In contest, claimant argued that under the reasonable medical basis standard, the attesting physician's conclusions should be accepted unless they are "extreme or excessive." Claimant also asserted that there is a reasonable medical basis for Dr. Johnson's conclusions because he participated in the Trust's Screening Program<sup>8</sup> and several echocardiograms, including one performed by Duck Chun, M.D., demonstrated that claimant had mild to moderate aortic regurgitation.<sup>9</sup> Claimant further asserted that she should

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7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Gierse's claim.

8. See Settlement Agreement § IV.A.1 (Screening Program established under the Settlement Agreement).

9. Claimant states that the Green Form was based on an October 4, 2004 echocardiogram. The Green Form, however,  
(continued...)

prevail because "[q]uantifying the level of regurgitation shown on an echocardiogram is inherently subjective."<sup>10</sup> Finally, claimant suggested that the Trust was not properly applying the reasonable medical basis standard established in the Settlement Agreement and that the auditing cardiologist simply substituted his own opinion for that of the attesting physician.<sup>11</sup>

The Trust then issued a final post-audit determination again denying Ms. Gierse's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Gierse's claim should be paid. On March 6, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6039 (Mar. 6, 2006).

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9. (...continued)  
reflects that the echocardiogram of attestation was performed on May 22, 2003.

10. In support of this argument, claimant submitted excerpts from the depositions of five (5) physicians from other proceedings. None of the testimony submitted by claimant, however, specifically addressed Ms. Gierse's echocardiogram.

11. Claimant also contended that the Trust should ensure that its auditing cardiologists do not have any "biases" against claimants. As there is no evidence of any "bias," this issue is irrelevant for resolution of this claim. Similarly, claimant referenced, without any substantive discussion, a number of filings in MDL 1203. As claimant has not attempted to establish how these filings entitle her to Matrix Benefits, they are not pertinent to the disposition of this show cause claim.

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 2, 2006, and claimant submitted a sur-reply on June 23, 2006. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issues presented for resolution of this claim are whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that she had moderate aortic regurgitation and a reduced ejection fraction less than 50%. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Gierse reasserts the arguments that she made in contest. In addition, claimant argues that there is a reasonable medical basis for the attesting physician's finding of moderate aortic regurgitation because it is not uncommon for two cardiologists to review the same echocardiogram and to find different levels of regurgitation.

According to claimant, "[n]either diagnosis is correct or incorrect; both fall within the realm of having 'a reasonable medical basis.'"<sup>12</sup> Ms. Gierse also asserts that it is an "impossibility" to determine that the attesting physician's Green Form representation as to the level of claimant's aortic regurgitation does not have a reasonable medical basis because Dr. Skotnicki concluded that Ms. Gierse's JH/LVOTH ratio was 22.7% while aortic regurgitation is considered moderate when the JH/LVOTH ratio is as low as 25%. Moreover, Ms. Gierse suggests that, although Dr. Kisslo reviewed claimant's echocardiogram and opined that the JH/LVOTH ratio did not measure 25% or more, "it can reasonably be inferred that ... Dr. Kisslo's own measurements calculated the jet very close to 25%."<sup>13</sup> Finally, claimant contends that there is a reasonable medical basis for the attesting physician's finding of a reduced ejection fraction as the M-mode report is visible on her echocardiogram.<sup>14</sup>

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12. Claimant also suggested that the auditing cardiologist was biased against her because he questioned whether Ms. Gierse ingested Diet Drugs. We disagree. As reflected in the Certification of Auditing Cardiologist, Dr. Skotnicki's conclusions were based on a review of claimant's medical records and echocardiogram.

13. Although claimant notes that a view other than the parasternal long-axis view "reinforces" the finding of moderate aortic regurgitation, Ms. Gierse concedes that this "other view" is not appropriately considered under the terms of the Settlement Agreement.

14. Claimant did not provide any medical support for this argument.



In response, the Trust disputes claimant's characterization of the reasonable medical basis standard. Moreover, the Trust argues that claimant failed to rebut any of Dr. Skotnicki's specific findings.

In her sur-reply, claimant reasserts that she should prevail because: (1) Dr. Johnson's Green Form representation should not be disregarded based solely on his earlier statement that Ms. Gierse suffered from mild to moderate aortic regurgitation; (2) interpretation of echocardiograms is "highly subjective"; and (3) the M-mode report calculates the ejection fraction at 40%.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not adequately contest Dr. Skotnicki's diagnoses of mild aortic regurgitation and a normal ejection fraction.<sup>15</sup> Despite the opportunity in the contest period to present additional evidence in support of her claim, Ms. Gierse rests only on Dr. Johnson's check-the-box diagnoses on her Green Form and the reports of several echocardiograms, including the report of the echocardiogram at issue in claimant's Green Form.<sup>16</sup>

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15. Dr. Skotnicki specifically measured claimant's aortic regurgitation at 22.7% and determined that claimant's ejection fraction was in the range of 62% to 65%.

16. In addition to the report of the echocardiogram at issue in claimant's Green Form, the Show Cause Record contains a report of a June 26, 1997 echocardiogram, which states that claimant had "a mild to moderate degree of aortic regurgitation." This report, prepared by Dr. Chun, however, did not specify a percentage as to  
(continued...)

Claimant never identified any particular error in the auditing cardiologist's measurements or conclusions. Mere disagreement with the auditing cardiologist without identifying any specific errors by the auditing cardiologist is insufficient to meet a claimant's burden of proof. On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

We also disagree with claimant's characterization of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the reasonable medical basis standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. Here, Dr. Skotnicki determined in audit, and Ms. Gierse does not adequately dispute, that the attesting physician's findings of moderate aortic regurgitation and a reduced ejection fraction were unreasonable. Specifically, Dr. Skotnicki measured claimant's JH/LVOTH to be less than 24%. With respect to her ejection fraction, Dr. Skotnicki concluded that Ms. Gierse's left ventricle contracted "very well."<sup>17</sup>

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16. (...continued)  
claimant's level of aortic regurgitation. Moreover, as we previously have held, a claimant cannot establish a reasonable medical basis for his or her claim simply by accumulating cardiologist opinions or echocardiogram reports.

17. Similarly, we disagree with claimant that the conflict between the attesting physician and the auditing cardiologist is due to the "subjective nature of echocardiography." Nor has  
(continued...)

Contrary to claimant's argument, Dr. Skotnicki properly applied the reasonable medical basis standard established under the Settlement Agreement.

Moreover, we reject claimant's assertion that she is entitled to Matrix Benefits merely because her echocardiogram was interpreted by a physician who participated in the Screening Program for Fund A Benefits under the Settlement Agreement. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit that an eligible class member is entitled to receive for a favorable echocardiogram performed in the Screening Program is a limited amount of medical services or a limited cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

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17. (...continued)

Dr. Skotnicki merely substituted his opinion for that of the attesting physician. Instead, Dr. Skotnicki specifically found that there was no reasonable medical basis for the attesting physician's findings. Neither claimant nor claimant's attesting physician, however, adequately refuted or responded to these determinations.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section § VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662, which mandated a 100% audit requirement for all claims for Matrix Benefits. See PTO No. 2662 at 13 (Nov. 26, 2002). As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.<sup>18</sup>

Finally, we disagree with claimant that there is a reasonable medical basis for her attesting physician's finding of moderate aortic regurgitation because "it is simply wrong to label a 2% difference as having no 'reasonable medical basis.'" The Settlement Agreement provides specific criteria to establish moderate aortic regurgitation. Nothing in the Settlement

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18. In any event, the report for the Screening Program echocardiogram simply states that the echocardiogram demonstrated "[m]ild, possibly moderate aortic insufficiency." Absent medical support for claimant's position that the Screening Program echocardiogram demonstrates the requisite level of aortic regurgitation required for a claim for Matrix Benefits, the Screening Program echocardiogram does not establish a reasonable medical basis for Ms. Gierse's claim.

Agreement allows a claimant to recover Matrix Benefits where the claimant relies on a measurement close to that required by the Settlement Agreement. To conclude otherwise would render meaningless this critical provision of the Settlement Agreement.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate aortic regurgitation and a reduced ejection fraction. Therefore, we will affirm the Trust's denial of Ms. Gierse's claim for Matrix Benefits and the related derivative claim submitted by her spouse.